

IN THE SPECIFICATION

[0089] Alternatively the signal interpretation may partly or completely take place in the CPU 180. An arbitrary waveform generator 190 or sine wave frequency generator will be used to send a composite waveform signal to the probe electrodes and tissue under test. The measured signal response (in the case of the composite wave form stimulus) may be deconvolved using FFT (Fast Fourier Transforms) in the DSP 130 or CPU 180 from which the impedance profile is measured under the different test conditions. An internal calibration reference 195 is used for internal calibration of the system for impedance measurements. DC calibration may be performed externally, calibrating the probe being utilized against an external reference electrolyte solution. As illustrated in Figure 1, an overload sensor is provided between the reference probe or nipple electrodes 110 and the internal calibration reference 195.

[0091] Referring to close-up 440, the ductal probe is inserted into one of several ductal orifices that open onto the surface of the nipple. Ductal probe 443 is shown within a ductal sinus 444, which drains a larger collecting duct 445. The handle 410 is illustrated in the closeup 440 at 441'.

[0094] Figure 3 illustrates the probe 400 of Figure 2 in greater detail. The skin contact of the surface 450 is placed in contact with the breast. The surface electrodes 451 measure DC or AC voltages. The current passing electrodes 452 are used for impedance measurements. Probe 400 may also include one or more recessed wells containing one or more ECMs, illustrated at 460. Multiple sensor electrode arrays may be attached to the surface probe together with current passing electrodes. The individual electrodes may be recessed and ECMs with different composition may be used to pharmacologically,

electrophysiologically, or hormonally probe the deeper tissues or epithelium under test. Spacing of the electrodes may be greater for the breast configuration than for other organ systems so that deeper tissue may be electrically probed and the impedance of the deeper tissue evaluated. This probe may either be placed passively in contact with the surface of the breast or held in place by pneumatic suction over the region of interest. Ports may be placed for the exchange of solutions or for fluid exchange and suction (not shown). Guard rings (not shown) may be incorporated to prevent cross-talk between electrodes and to force current from the contact surface into the breast. In this configuration there are four current passing electrodes [453] each positioned radially 90° apart. This permits current to be passed and the voltage response to be measured in perpendicular fields. The electrodes will be interfaced via electrical wire, or wireless technology, with the device described in figure 1 above.

[0096] Figure 4 illustrates a nipple cup electrode [500] that may be used as a reference, current passing, voltage measuring or combination electrode [502]. In this configuration suction and fluid exchange is applied to the electrode housing [501] through a side port [510] connected by a flexible hose [515] to a suction device, aspirator or syringe (not shown). The flange [503] at the base of the cup is applied to the areola of the breast [520]. Pneumatic suction is applied through the side port and communicated to the housing by passage [512] so as to obtain a seal between the breast [520] and the nipple electrode [501]. Electrolyte solution is used to fill the cup and make electrical contact with the underlying ductal system. Fluid may be exchanged, or pharmacological and hormonal agents introduced, by applying alternating suction and injecting fluid or drugs into the cup through the side port. The pneumatic suction will

open up the duct openings [505] either by itself or after preparation with alcohol or de-keratinizing agents to remove keratin plugs at the duct openings at the surface of the nipple. The nipple cup electrode [502~~500~~] may be interfaced by means of an electrical connection [530] or by a wireless connection (not shown) with the devices illustrated in figures 1-3 to obtain DC potential, AC impedance or combination measurements.

[0097] Figure 5 illustrates an alternative approach where an individual duct is probed with a flexible catheter electrode [550] attached to a syringe [555]. This may be used when a specific duct produces fluid and diagnosis is to be performed on the specific ductal system producing the fluid. In this configuration a saline filled syringe is connected to a flexible electrode [550], which is inserted into the duct [551]. Fluid may be exchanged, or drugs and hormones may be infused into the duct, through the catheter. An electrode within, or attached to the syringe makes electrical contact with the individual ductal system, and the surface probe electrodes [552] complete the circuit so that the DC potential, AC impedance or a combination of both may be measured across the ductal epithelium, skin and intervening breast parenchyma, as illustrated schematically by the gauge shown at [553], in combination with the systems described in figures 1-3. Another approach would be to use a ductoscope in combination with a surface probe with the electrode(s) interfaced with the ductoscope.